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December 20, 2004

Division of Dockets Management
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203 and 2000N-0504, "Prevention of *Salmonella* Enteriditis in Shell Eggs during Production"

Greetings:

Thank you for the opportunity to submit these written comments to the Federal Drug and Food Administration (FDA). We are an egg production, processing and further processing company with operations in Minnesota, Colorado, and primarily Iowa. We currently have 12,500,000 layers under our ownership or control and are the fifth largest and fourth largest company, respectively, in the fresh shell table egg and further egg processing businesses in the United States.

We are dedicated to providing a safe product to our customers. We presently follow the United Egg Producers Five Star Quality Assurance program and treat food safety as an important issue/concern within this company.

Although our reading of the proposed rule notes twenty-seven (27) instances of where you are inviting comment to the docket, we will none-the-less keep our comments limited herein to the issues which we feel are most important and material to the stated and intended purpose of the proposed regulation. In addition, we want you to know we have reviewed the submitted comments of the United Egg Producers, the Broiler and Egg Association of Minnesota, the Iowa Poultry Association, Rose Acres Farms, the State of Minnesota Department of Agriculture in conjunction with the Department of Animal Sciences at the University of Minnesota, as well as the comments of Warehouse Shell Sales Company and Global Poultry Marketing Services, amongst others, and take no exception nor have anything to add to or contrary of the comments submitted by the aforementioned. Indeed, we wholeheartedly support the comments of all industrial representatives (allied included) who have submitted comments.

In addition, we have also read the comments of, and consulted with a number of the individuals on the subcommittee that drafted the comments on behalf of the United States Animal Health Association (USAHA). Our company veterinarian is also a member of that association. The individuals on the USAHA subcommittee that drafted their submitted comments comprise a group that know more about SE, and reduction or elimination thereof, than anyone in the world. We stand behind, the comprehensive comments that they have submitted.

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Recognition of Existing Efforts

FDA should recognize that many states and egg production and processing enterprises have already adopted egg quality assurance programs. If such programs are functionally equivalent to FDA requirements, then producers or processors following them should be considered in compliance with FDA's regulations.

Vaccination

We believe the option of using a vaccination program should be available for producers wishing to pursue such a program. It is our understanding data exists in the United States and in Europe which documents the efficacy of vaccination programs. Under a vaccination regimen, we do not believe egg producers should be required to do environmental testing at the 45-week and 22-week time periods but instead would do environmental testing at the time the flock is disposed of (depopulated). We support the submitted written comments of the vaccination companies that have sent comments on this issue.

A vaccination program should cover the risk reduction associated with Salmonella Enteriditis (SE) that the FDA seeks. The intention of the program is to have a twelve (12) log reduction in SE isolates. According to data we have reviewed, a viable vaccination program can accomplish this without "any" further changes. FDA should encourage these vaccination programs and, as such, limit environmental testing requirements and cleaning of the building and equipment requirements as a reward for those utilizing a viable vaccination program.

Cleaning and Manure Handling

Should an environmental positive be identified, the producer should pursue a dry cleaning of the building. We do not believe wet cleaning should ever be used due to problems inherent in the process. Wet cleaning can wreak havoc on the metal equipment in a building and can substantially reduce the building's useful life. Requiring wet cleaning in Northern states in cold seasons would also prove quite problematic.

Wet cleaning has also been shown, in some studies, to actually increase SE. It is difficult to comprehend why the agency would propose a process that could actually increase the prevalence of SE, when the purpose of the proposed rule is to decrease the incidence of the organism.

The handling of the manure will also be problematic and requirements must remain flexible enough to allow the removal of manure only during times when it can be transported and applied to fields over a short period of time. The requirement that all "visible manure" be removed is unrealistic as some residue will always remain in porous building materials. The regulation must be realistic and practical.

Bio-security

The use of bio-security measures should be specific and tailored to farms and not simply "buildings" in general. Included in this area is the issue of clothing and footwear. This too should be farm specific instead of building-specific.

Other Establishments

This proposal does not address the concept of "cooking" the eggs. If food safety related to eggs is truly the purpose of this proposal, then FDA has the responsibility of ensuring all handlers of the eggs or egg products are storing, handling and cooking them in the appropriate manner.

Processing Issues

Egg further processing facilities need to be able to recover as much liquid product as is possible from the eggs. If eggs are held at too cool of a temperature this will not happen. Where the egg product will be pasteurized in processing, FDA should allow the eggs to achieve a warmer temperature prior to processing. The proposal's requirement that eggs held more than 36 hours be held at 45° F is unreasonable and unduly burdensome where processing will pasteurize the egg product. FDA should also allow the storage of shell eggs on-farm and prior to processing at temperatures not to exceed 60°F for a maximum time period of 5-days prior to processing. This will allow for the potential short-term storage and transportation of the shell eggs to the processing plant and the slow cool down of the shell eggs to maintain integrity and prevent thermal checks during shell egg processing.

The proposal's requirement that eggs held more than 36 hours be held at 45° F is unreasonable and unduly burdensome particularly where further processing will pasteurize the egg product.

Timing of Testing

The proposal's requirements for implementing testing after the discovery of an environmental positive are too short. If the proposal is to move forward, it should be changed to allow "up to 72-hours" time period between the finding of an environmental positive and the required egg testing. This allows for weekends or holiday weekends when laboratory facilities would most likely not be available to complete the test. In addition, has the agency even determined if lab capacity is adequate for the rule as proposed?

Husbandry Practices

We do not believe FDA has jurisdiction with regard to molting as a husbandry practice. We would suggest the agency review recent research that demonstrates molting has little if any impact on SE shedding from the hens. FDA should rely only on peer-reviewed, duplicative, valid and sound science for making decisions that will affect an entire U.S. industry.

Program Administration

USDA - AMS already inspects egg packing facilities four times per year under the Shell Egg Surveillance Program. If the proposed rule is adopted, the AMS should be in charge of administering this program since the vast majority of egg producers and processors have long histories of working with this agency, and its associated state and federal employees. Utilizing existing resources avoids the diversion of FDA employees from other important work.

Application to All Producers

The current proposal exempts producers with fewer than 3,000 laying hens. However, again, if food safety is the purpose of the proposal, exempting hens based on the size of the operation

eviscerates the alleged purpose. It is not the size of laying operation but rather the practices followed that create the safe food we enjoy in this country. To allow smaller producers to avoid food safety simply due to size exposes the entire industry to issues of credibility. Should problems arise, "eggs" are going to be blamed regardless the nature of the operation involved. More importantly, exemptions based on size expose people to food safety issues based on factors unrelated to food safety. Again, if a viable vaccination program was to be used, many of the financial burdens that a small producer would be subject to could be eliminated.

Let us reiterate that the Sparboe Companies are extremely concerned with the safety of the product we produce. However, we recognize that no matter what we do, we will never be able to make our product 100% safe. It is our opinion that the costs associated with this program are grossly underestimated. Even if we use the FDA numbers of 1 egg per 20,000 that may contain SE and an annual consumption of 190 shell eggs per person per year, an individual would only need to worry about 1 egg every 105 years. If that one egg is properly cooked, there would be no risk of SE contamination.

Our comments included herein reflect or mirror those comments and suggestions made by other egg producers that we have discussed this matter with. (See also the comments we offered at the public hearing on this matter in Chicago on November 9, 2004.) We would be less than honest if we were to say that there is universal agreement with the proposed rule within our industry. There is not. However, we believe that the above referenced matters need to be addressed. We look forward to the final proposal being in a workable format that best suits the stated intentions of the proposed regulations and accomplishes those objectives in the least intrusive and cost effective manner possible.

Thank you.

Sincerely yours,

Robert D. Sparboe
President

Greg Murch
Sr. Vice President, Operation

John W. Mueller
General Counsel

Hugo Medina
Technical Services Veterinarian

Cc:

United Egg Producers
Broiler and Egg Association of Minnesota (BEAM)
Iowa Egg Council/Iowa Poultry Association
Senator Chuck Grassley, Iowa
Senator Tom Harkin, Iowa
Senator Ben Nighthorse Campbell, Colorado
Senator Wayne Allard, Colorado
Senator Mark Dayton, Minnesota
Senator Norm Coleman, Minnesota
Congressman Collin Peterson
Congressman Tom Latham
Congressman Mark Kennedy
USAHA
Rose Acre Farms